

### **REMARKS**

The pending Office Action addresses claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30-39, and 42-53, all of which stand rejected. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

#### ***Amendments to the Claims***

Applicants present the following claim amendments solely to expedite prosecution. These amendments should not be construed as Applicants' acceptance of the Examiner's rejection. Applicants reserve the right to prosecute any of the former claims in a continuing application.

Claims 1 and 13 are amended to recite that the viable tissue comprises naturally occurring cells and their extracellular matrix, and that the viable tissue is minced to form finely minced tissue fragments. Claim 24 is amended to recite obtaining a viable tissue comprising naturally occurring cells and their extracellular matrix and mincing the viable tissue to form finely minced tissue fragments. Claim 34 is amended to recite obtaining a viable tissue comprising naturally occurring cells and their extracellular matrix and preparing the viable tissue to form finely minced tissue fragments. Claims 43, 47, 49, and 53 are amended to recite that at least a portion of the scaffold is capable of being populated with cells from the native tissue following implantation.

Support for these amendments can be found throughout the specification, for example at paragraphs [0059] and [0065]. No new matter is added.

#### ***Rejections Pursuant to 35 U.S.C. §101***

Claims 43, 47, 49, and 53 are rejected pursuant to 35 U.S.C. §101 as being directed to non-statutory subject matter. The Examiner asserts that the claims affirmatively claim "the cells of the native tissue." Claims 43, 47, 49, and 53 are amended to recite that at least a portion of the scaffold *is capable* of being populated with cells from the native tissue following implantation. Applicants submit that claims 43, 47, 49, and 53, as amended, comply with 35 U.S.C. §101.

### ***Rejections Over Brekke***

Claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30, 31, 34-39, and 42-53 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,005,161 of Brekke et al. ("Brekke"). Applicants respectfully disagree with the Examiner's rejection.

Brekke is directed to a biodegradable graft device for the repair of articular cartilage. The device of Brekke is composed of a porous, biodegradable polymeric macrostructure containing a chemotactic ground substance and osteoinductive or osteogenic substances. The biodegradable graft device may also act as "a carrier for cells which have demonstrated the ability to differentiate into cartilage cells, i.e. bone marrow, periosteal, or perichondrial cells, with the latter being preferred." Col. 10, lines 42-45. The precursor cells are harvested from tissue by "1) placing the precursor tissue in culture and allowing the *cells to proliferate out of the tissue*, or 2) digesting the tissue with collagenase, thereby *freeing the cells*, which in turn are placed in the culture medium and grown." Col. 11, lines 42-49 (emphasis added). Brekke additionally discloses attaching a tissue slice to the surface of the biodegradable device. "As tissue, perichondrium and periosteum are *cut to the desired size of the biodegradable device* and can be attached to the biodegradable device by a suturing technique as diagrammatically shown in FIG. 7." Col. 11, lines 14-18 (emphasis added).

#### **Claim 1**

Claim 1 recites a wedge-shaped porous tissue scaffold having a pocket containing a viable tissue having cells capable of migrating into the scaffold. The viable tissue comprises naturally occurring cells and *their* extracellular matrix, and the viable tissue is minced to form finely minced tissue fragments.

Brekke fails to teach a viable tissue comprising *naturally occurring cells and their extracellular matrix*, wherein the tissue is *minced to form finely minced tissue fragments* within a pocket of a tissue scaffold. Rather, Brekke discloses seeding the biodegradable device with a suspension of *cultured cells* or attaching a *tissue slice* to the biodegradable device.

The suspension of cells lacks the cells' extracellular matrix as Brekke discloses *digesting the extracellular matrix* prior to culturing the cells or, in the alternative, culturing the cells to *proliferate*

*the cells out of the tissue's extracellular matrix.*

In the embodiment of Brekke comprising attaching a tissue slice to the biodegradable device, the tissue is neither minced to form finely minced tissue fragments nor contained within a pocket of the scaffold, as required by claim 1. Rather, the tissue of Brekke comprises a slice of tissue that is *cut to the size of the biodegradable device* and sutured to an *outer surface* of the device. Although the Examiner characterizes the phrase "cut to the desired size of the biodegradable device" as meaning that "the tissue size can be optimized to the desired need of the patient" and thereby includes tissue fragments, *Office Action* dated Dec. 11, 2008, page 4, Figure 7 of Brekke plainly shows that the size of the tissue slice corresponds to the size of a surface of the biodegradable device. Further, Brekke does not even suggest mincing tissue as the resulting fragments could not be *sutured* to a surface of the device as taught by Brekke. Thus, the specification and figures do not support the Examiner's characterization. Accordingly, Brekke fails to teach a viable tissue comprising *naturally occurring cells and their extracellular matrix*, wherein the tissue is *minced to form finely minced tissue fragments* within a pocket of a tissue scaffold.

Claim 1, therefore, distinguishes over Brekke and represents allowable subject matter. Claims 3-6, 9, 10, 42, and 43, which depend therefrom, are allowable at least because they depend from an allowable base claim.

#### Claim 13

Claim 13 recites a viable tissue disposed within a pocket of the tissue scaffold, wherein the viable tissue comprises *naturally occurring cells and their extracellular matrix* and the viable tissue is *finely minced to form minced tissue fragments*.

As discussed above with reference to claim 1, Brekke fails to teach a viable tissue comprising *naturally occurring cells and their extracellular matrix* within a pocket of a tissue scaffold, wherein the viable tissue is *finely minced to form minced tissue fragments*.

Accordingly, claim 13 distinguishes over Brekke and represents allowable subject matter. Claims 14-18, 20, 21, and 44-47, which depend therefrom, are allowable at least because they depend from an allowable base claim.

Claim 24

Claim 24 recites obtaining a viable tissue comprising naturally occurring cells and their extracellular matrix, mincing the viable tissue to form finely minced tissue particles, and loading the viable tissue into a pocket of the scaffold.

As discussed above with reference to claim 1, Brekke fails to teach mincing a viable tissue comprising naturally occurring *cells and their extracellular matrix* to form *finely minced tissue particles*.

Accordingly, claim 24 distinguishes over Brekke and represents allowable subject matter. Claims 25-28, 30, 31, 48, and 49, which depend therefrom, are allowable at least because they depend from an allowable base claim.

Claim 34

Claim 34 recites a method for repairing defective tissue comprising obtaining a viable tissue comprising naturally occurring cells and their extracellular matrix and preparing the viable tissue to form finely minced tissue fragments.

As discussed above with reference to claim 1, Brekke fails to teach preparing a viable tissue to form *finely minced tissue fragments*.

Accordingly, claim 34 distinguishes over Brekke and represents allowable subject matter. Claims 35-39 and 50-53, which depend therefrom, are allowable at least because they depend from an allowable base claim.

***Rejections Over Schwartz***

Claims 1, 3-6, 9, 10, 13-18, 20, 21, and 42-47 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/78617 of Schwartz et al. ("Schwartz"). Claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30, 31, 34-39, and 42-53 are also rejected pursuant to 35 U.S.C. §103(a) as being obvious over Schwartz.

As shown in Figure 23, Schwartz discloses a device for regenerating intra-articular cartilage

having a base (21) that contains a tissue regeneration material (22). The base (21) is formed of a biocompatible polymer, a bioremodelable collagenous matrix, or a *naturally occurring ECM* (e.g., SIS). Paragraph [0108]. The tissue regeneration material (22) “encompasses *naturally-occurring extracellular matrix* (ECM) materials that provide a *collagen scaffold* for tissue repair and regeneration.” Paragraph [0083] (emphasis added). Schwartz defines “naturally occurring extracellular matrix” at paragraph [0083], as follows:

Thus, in this application, the terms “naturally occurring extracellular matrix” or “naturally occurring ECM” are intended to refer to *extracellular matrix material that has been cleaned, disinfected, sterilized, and optionally cross-linked*. The terms “naturally occurring ECM” and “naturally occurring extracellular matrix” are intended to include foam material made from naturally occurring ECM....”

Thus, Schwartz provides a tissue regeneration material (22) comprising a *collagen scaffold* formed of processed, decellularized extracellular matrix.

#### Claim 1

Schwartz fails to teach a viable tissue comprising *naturally occurring cells and their extracellular matrix*. Although the Examiner characterizes the tissue regeneration material (22) of Schwartz as viable tissue, the tissue regeneration material consists of *extracellular matrix material* that has been cleaned, disinfected, sterilized, and cross-linked. Thus, Schwartz explicitly limits tissue regeneration material to the extracellular collagen scaffold that is present between cells. Accordingly, the tissue regeneration material of Schwartz lacks the cells and their extracellular matrix, as required in claim 1. Additionally, Schwartz fails to disclose a viable tissue *minced to form finely minced tissue fragments*. The passages cited by the Examiner as disclosing minced tissue are instead directed to “comminuted ECM material.” Para. [0016]. As discussed above, ECM material does not include cells and their extracellular matrix. Accordingly, there is no teaching by Schwartz to mince anything containing cells. Thus, Schwartz fails to teach a scaffold having a pocket containing a *viable tissue minced to form finely minced tissue fragments*.

Accordingly, claim 1 distinguishes over Schwartz and represents allowable subject matter. Claims 3-6, 9, 10, 42, and 43, which depend therefrom, are allowable at least because they depend from an allowable base claim.

Claim 13

As discussed above with reference to claim 1, Schwartz fails to teach a viable tissue comprising *naturally occurring cells and their extracellular matrix* within a pocket of a tissue scaffold, wherein the viable tissue is *finely minced to form minced tissue fragments*.

Accordingly, claim 13 distinguishes over Schwartz and represents allowable subject matter. Claims 14-18, 20, 21, and 44-47, which depend therefrom, are allowable at least because they depend from an allowable base claim.

Claim 24

As discussed above with reference to claim 1, Schwartz fails to teach mincing a viable tissue comprising *naturally occurring tissue and their extracellular matrix to form finely minced tissue particles*.

Accordingly, claim 24 distinguishes over Schwartz and represents allowable subject matter. Claims 25-28, 30, 31, 48, and 49, which depend therefrom, are allowable at least because they depend from an allowable base claim.

Claim 34

As discussed above with reference to claim 1, Schwartz fails to teach preparing a viable tissue to form *finely minced tissue fragments*.


Accordingly, claim 34 distinguishes over Schwartz and represents allowable subject matter. Claims 35-39 and 50-53, which depend therefrom, are allowable at least because they depend from an allowable base claim.

***Conclusion***

In conclusion, Applicants submit that all claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Dated: April 9, 2009

Respectfully submitted,

By   
Lisa Adams  
Registration No.: 44,238  
NUTTER McCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617) 439-2550  
Fax: (617) 310-9550  
Attorney for Applicants

1817280.1